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SENSITIVE
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SUBJECT: CROATIA IPR UPDATE

SENSITIVE BUT UNCLASSIFIED

¶1. (SBU) Summary: Croatia is currently not on the Special 301 Watch List. Post has researched the area of concern identified by industry in its Special 301 submission (see paragraph 4). Croatia's legal framework continues to develop and is now completely harmonized with the EU. However, effective law enforcement, including addressing of IPR issues in the courts, is uneven and often does not provide companies adequate IPR protection. Post has recently engaged in advocacy for a U.S. pharmaceutical company facing patent violations by a generic producer. Post's efforts have achieved a positive result, but Croatia still faces problems of patent protection in its licensing procedures for new drugs. End Summary.

Legal framework Now Harmonized with EU

¶2. (SBU) With the recent passage of several pieces of technical legislation, the legal framework for the protection of IPR in Croatia is fully harmonized with the Acquis Communautaire. IPR infringements have been criminalized in Croatia since 1994. Until recently, the Ministry of Interior maintained a special IPR investigative police unit. This unit was recently absorbed into the department of white collar crime and has ceased to exist on its own. Several U.S. companies in the country have complained about this move, saying they no longer have any specific counterparts in the police with whom to discuss IPR cases.

¶3. Seizures and the number of criminal cases brought for IP crimes have risen steadily in recent years, however problems remain. Geography poses Croatia's greatest challenge in protecting IPR, as its long coast and land borders with Bosnia and Serbia make it a major transit route for counterfeit goods. Also, despite regular police seizures of pirated and counterfeit goods, Croatia's court system has not developed as far in its ability to tackle this problem, frequently releasing violators with little more than a verbal warning and forfeiture of goods seized. Post has an excellent relationship with the government IPR office and they have expressed their openness to suggestions or assistance that the USG can offer in relation to IPR issues.

Twinning project to intensify IPR enforcement

13. (SBU) Croatia recently received approval for the PHARE 2006 twinning project "Strengthening the Enforcement of Intellectual Property Rights" launched in February 2009. The project is designed to train relevant persons in the Ministry of Justice, Ministry of Interior, Customs Authority and the State Inspectorate in effective law enforcement techniques. The project is intended to strengthen administrative capacity in line with legislation harmonized with the EU. While Croatia is not an important producer of pirated and counterfeit goods, the authorities involved will increase levels of information sharing that should lead to increased actions against entrance of and distribution of counterfeit goods in Croatia.

Interpretation of .hr domain legislation

14. (SBU) Post has researched a concern received this year from the business community - Verizon's "Special 301" submission, which mentions a problem with Croatia's internet domain regulations. After discussions with CARnet, Croatia's official .hr domain source, post believes Verizon has misinterpreted Croatia's regulations. A CARnet representative explained that while a company registered in Croatia may apply for only one domain, the domain name itself is not restricted. Verizon's example of an infringer registered as "verizon.hr" precluding the company from

ZAGREB 00000152 002 OF 002

registering as "verizontelecom.hr" is not correct. A company registered in Croatia may use any word and symbol they wish in their domain name and may use only a symbol or add a word to differ from an already registered .hr domain.

Qualified success on a recent IPR issue

15. The issue of patent linkage between medical licensing agencies and patent enforcement entities continues to be a problem in Croatia. (Note: An MOU signed between the state IPR office and the medical licensing agency in 2007 on information sharing led to Croatia's removal from the Special 301 Watchlist.) Despite this MOU, local representatives of Merck pharmaceuticals approached the embassy last fall to report that Krka Pharmaceuticals, a Slovenian pharmaceutical company, had registered a generic form of MSD's patented Singulair asthma medicine with the Medical Licensing Agency. Although the patent registered to Merck expires on October 11, 2011, Krka was able to register the generic copy of the drug in Croatia under the name Monkasta and has submitted a request to the Croatian Health Insurance Fund (HZZO) for the drug to be included on the HZZO reimbursement list. The Croatian Patent Act allows this procedure per Article 112, which does not allow for standard patent protection for patents registered before 1993, but only allows holders of such patents to initiate court proceedings in order to claim damages. Hence, Merck cannot prevent the marketing of Singulair's copies in Croatia regardless of the existing patent, but can only seek compensation in court. This loophole is not unique to Croatia, and we understand that most EU countries have similar legislation. However, most EU countries' judicial systems are more efficient in ruling in a timely and effective manner on behalf of the

damaged party.

¶16. After numerous discussions between Merck, Embassy econ and FCS officers, the state IPR office, the medical licensing agency, and the Ministry of Health, the HZZO recently put off decision on the approval of the Krka drug for their reimbursement list until at least July. Merck is please with this situation for the moment and told us the embassy's assistance had helped save them \$3 million in sales.

¶17. Comment. We were disappointed to see the issue of patent linkage arise again after the signing of the MOU between the state IPR office and the medical licensing agency. The licensing agency clearly does not feel it has an obligation to consult with the patent office and has told us they are not authorized to make decisions taking patent rights into consideration. Despite this problem, Croatia's legal framework is strong. What lags behind is enforcement, both in police and customs capacity, and knowledge of IPR within the court system. Any bilateral assistance efforts in the future should focus on these areas.

BRADTKE